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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/580,462	05/26/2000	Stephen Fox Heinemann	SALK1590-3	2034
30542	7590	02/03/2005	EXAMINER	
FOLEY & LARDNER P.O. BOX 80278 SAN DIEGO, CA 92138-0278			ULM, JOHN D	
			ART UNIT	PAPER NUMBER
			1646	

DATE MAILED: 02/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/580,462

Applicant(s)

HEINEMANN ET AL.

Examiner

John D. Ulm

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 November 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 7 and 34-48 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 7,35-37 and 45-48 is/are allowed.
- 6) ☒ Claim(s) 34 38-44 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

1) Claims 7 and 34 to 48 are pending in the instant application. Claims 34 to 39 have been amended and claims 45 to 48 have been added as requested in the correspondence filed 23 November of 2004.

2) Any objection or rejection of record that is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

3) The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4) Claims 7, 35 to 37 and 45 to 48 are allowable as written.

5) Claim 38 stands objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim for those reasons of record in section 7 of the previous office action. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. A properly dependent claim can not conceivably be infringed without infringing any of the claims from which it depends. Claim 38 can be infringed by a polynucleotide composition that does not infringe claim 7. See M.P.E.P. 608.01(n)III.

6) Claims 34 and 39 to 44 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement for those reasons of record as applied to claims 34 and 36 to 44 in section 8 of the previous office action and as applied to claims 5, 8, 9 and 11 to 17 in section 6 of the office action mailed 22 October of 2001. As essentially stated therein, the instant specification does not describe a nucleic acid that is encompassed by the instant claims that does not encode the amino

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acid sequence presented in Figures 9A to 9C of the instant application. Applicant essentially traverses this rejection on the premise that the instant claims now recite the combination of functions recited therein. This is not persuasive because there is no correlation between the structural limitations recited in the claims and the functional limitation recited therein.

7) Claims 34 and 39 to 44 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement for those reasons of record as applied to claims 34 and 36 to 44 in section 8 of the previous office action. As stated therein, the instant claims encompass a polynucleotide "encoding a beta2 subunit of a neuronal acetylcholine receptor" having other than that single, naturally occurring amino acid sequence presented in Figures 9A to 9C of the instant application. The instant specification, however, does not provide the guidance that would be needed by a artisan to produce a functional neuronal acetylcholine receptor beta2 subunit protein having anything other than the naturally occurring amino acid sequence presented in the instant specification without resorting to a substantial amount of undue experimentation.

Applicant has traversed this rejection on the premise that one could readily isolated related nucleic acids. Applicant is advised that the instant claims are not limited to naturally occurring nucleic acid or nucleic acids encoding naturally occurring proteins. Further, Applicant's arguments are in complete conflict with the judicial precedents upon which the two preceding rejections are based.

8) Claims 34 and 39 to 44 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

8.1) Claims 34 and 39 to 44 are vague and indefinite in reference to the term "beta2" for those reasons of record.

8.2) Claims 39 to 41 are vague and indefinite because the limitation "under high stringency conditions" is conditional and no specific, defining set of hybridization conditions is recited in the specification or the claims.

8.3) Claims 42 to 44 are vague and indefinite because the instant specification does not identify that property or combination of properties which is unique to and, therefore, definitive of an alpha2, alpha3, alpha4, alpha5, beta3 or beta4 receptor subunit, rendering it impossible to determine the metes and bounds of these claims.

9) Applicant's arguments filed 23 November of 2004 have been fully considered but they are not persuasive.

10) **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John D. Ulm whose telephone number is (571) 272-0880. The examiner can normally be reached on 9:00AM to 5:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Caputa Anthony can be reached on (571) 272-0829. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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